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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,492	02/12/2001	Charles Nicolette	20363-004 (DFCI-4)	7050

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EXAMINER	
LI, QIAN J	
ART UNIT	**PAPER NUMBER**
1632	11

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,492	NICOLETTE ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,35-39,42,45-49,52-55,84,89 and 90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,35-39,42,45-49,52-55,84,89 and 90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment and response filed 1/29/03 has been entered as paper No. 10. Claims 1-31, 33, 34, 40, 41, 43, 44, 50, 51, 56-83, and 85-88 have been canceled, and claims 89 and 90 are newly submitted. Claims 32, 35-39, 42, 45-49, 52-55, 84, 89, and 90 are pending and under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The prior rejection of claims 32-55, 84, and 85 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of claims 32-55, 84, and 85 under 35 U.S.C. 112, first paragraph, is with drawn in view of the claim amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 35, 42, 45, and 84 stand rejected under 35 U.S.C. 102(e) as being anticipated by *Nair et al* (US 6,306,388).

In paper #10, applicants argue that *Nair et al* do not teach or suggest contacting a CTL with a hybrid cell as recited in the amended claims.

The argument has been fully considered but they are not persuasive. This is because claims are drawn to a substantially pure population of educated, antigen-specific immune efffector cells, therefore, as long as *Nair et al* teach a population of such antigen specific immune effector cells, the claim limitations are met regardless how the cells are made, i.e. by co-culturing with hybrid cells or non-hybrid antigen-presenting cells. It was indicated previously and reiterates here, that patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). Therefore, in the absence of the evidence that the use of hybrid cells produces a population of structurally distinct immune effector cells, *Nair et al* anticipate instant claims.

Claims 32, 35, 42, 45, and 84 stand rejected under 35 U.S.C. 102(e) as being anticipated by *Granucci et al* (6,156,307).

In paper #10, applicants argue that *Granucci et al* do not teach or suggest contacting T lymphocytes with hybrid cells as required by the instant claims, and do not teach or suggest the use of the specific hybrid cells of the present invention.

The argument has been fully considered but they are not persuasive. This is because claims are drawn to a substantially pure population of educated, antigen-specific immune efffector cells, therefore, as long as *Granucci et al* teach a population of such antigen-specific immune effector cells, the claim limitations are met regardless how the cells are made, i.e. by co-culturing with hybrid cells or non-hybrid dendritic cells. It was indicated previously and reiterates here, that patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it, which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). Therefore, in the absence of the evidence that the use of hybrid cells produces a population of structurally distinct immune effector cells, *Granucci et al* anticipate instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32, 35-39, 42, 45-49, 52-55, 84, stand rejected, and the rejection applies to new claims 89 and 90 under 35 U.S.C. 103(a) as being unpatentable over *Granucci*

et al (US 6,156,307) as applied to claims 32, 35, 42, 45, and 84 above, and in view of *Moser et al* (WO96/30030, PTO-1449/B1).

In paper #10, Applicants argue that *Granucci et al* do not teach the use of the specific hybrid cells of the present invention, and the addition of Moser does not cure the deficiencies because the hybrid cells made by *Moser et al* do not meet claim limitations as recited in the amended claims.

The argument has been fully considered but they are not persuasive. This is because claims are drawn to a substantially pure population of educated, antigen-specific immune efffector cells, therefore, as long as the combined teachings of *Granucci et al* and *Moser et al* disclose a population of such antigen-specific immune effector cells, the claim limitations are met regardless how the cells are made, i.e. by the same type of hybrid cells or otherwise. It was indicated previously and reiterates here, that patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it, which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). Therefore, in the absence of the evidence that the use of hybrid cells produces a population of structurally distinct immune effector cells, the rejection stands.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
April 3, 2003

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER